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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/598,080
Filing Date: September 07, 2006
Appellant(s): GALL ET AL.

Wm. Alex Furman
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed April 18, 2011 appealing from the Office action mailed September 28, 2010.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 46, 51, 52, 55, 56, 139-141 are rejected.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

Art Unit: 3733

2002/0165547	Dovesi	11-2002
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5,505,735	Li	4-1996
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Lendlein et al., Biodegradable, Elastic Shape-Memory Polymers for Potential Biomedical Applications, Science, Vol.. 296, pp. 1673-1676 (May 31, 2002).

(9) Grounds of Rejection

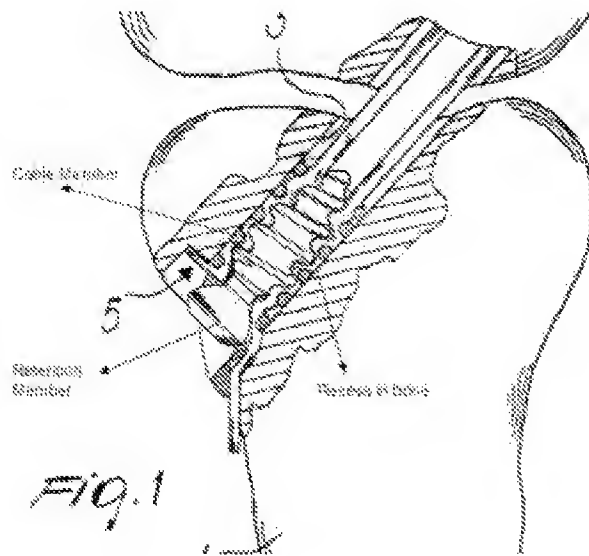
The following ground(s) of rejection are applicable to the appealed claims:

Claims 46, 51, 55, 139 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dovesi et al US 2002/0165547 in view of Lendlein et al (see IDS filed on 7/29/2010, NPL #66).

Regarding **Claim 46**, Dovesi discloses a method comprising:

inserting a cable member (#6) into a recess in a bone (see Fig below as well as Figs 2-4);

inserting a retention device (#7) into the recess, the retention device containing a shape memory material; and activating the shape memory material (as seen in Fig below and see paragraph 25-26, 30, where shape memory material can be used, where shape memory materials are known in the art for their ability to change shape when activated).



Regarding **Claim 51**, Dovesi discloses creating the cable member is selected from an animal tissue, a synthetic fiber, a natural fiber, a polymer, a metallic wire, a bundle, and a composite (as seen in Fig 2-4 and paragraph 30). Regarding **Claim 55**, Dovesi discloses the inserting the cable member operation precedes the inserting the retention device operation (see paragraph 25).

Dovesi discloses the use of a shape memory material, where the retain device applies a compressive force to the cable member against the bone (see paragraph 27) but does not disclose the retention device containing a shape memory polymer such that is inserted in a temporary pre-implantation shape and causing the polymer to change shape after implantation, thereby fixing the cable member to the bone with the retention device.

Art Unit: 3733

However, Lendlein discloses that shape memory polymers allow for implants to be placed through small incisions (see introduction on page 1673), wherein shape memory polymers possess the ability to memorize permanent shape that can substantially differ from their initial temporary shape, wherein bulkier devices can be introduced into the body in a compressed temporary shape then expanded on demand to a permanent shape to fit as required (see last paragraph at the end of page 1673 continuing to the top paragraph of page 1674), wherein the shape memory polymer can be activated by heating (see page 1674, 2nd and 3rd paragraphs starting with “The thermally induced shape memory effect ...”).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Dovesi to include a shape memory polymer in view of Lendlein because shape memory polymers are known shape memory materials, wherein shape memory polymers allow for implants to be placed through small incisions, where shape memory polymers possess the ability to memorize permanent shape that can substantially differ from their initial temporary shape, wherein bulkier devices can be introduced into the body in a compressed temporary shape. The combination of Dovesi and Lendlein would allow for the retention device to be inserted in a smaller pre-implantation shape through a smaller incision, where after the shape memory polymer is activated, the retention device would change to a larger shape, thereby providing additional fixation for the retention member in the bone as well as the cable member.

Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable Dovesi et al US 2002/0165547 and Lendlein et al (see IDS filed on 7/29/2010, NPL #66), as applied to claim 46, 51 above, and in further view of Chan US 2002/0188298.

The combination of Dovesi and Lendlein disclose the claimed invention as discussed above, where the cable member can be natural or synthetic but does not disclose that it is made from human soft tissue.

However, Chan discloses a similar method with a cable member (L) and a retention device (#1 as seen in Fig 2), wherein the cable member is made from a human donor or the patient itself (see paragraph 8-9), wherein human tissue is a known material used for ligament construction/cable member construction (see paragraphs 6-9).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of Dovesi and Lendlein to have the cable be made out of human soft tissue in view of Chan because human tissue is a known material used for ligament construction/cable member construction. It would have been further obvious to one having ordinary skill in the art at the time the invention was made to have the cable member be made out of human soft tissue, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claims 140-141 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dovesi et al US 2002/0165547 and Lendlein et al (see IDS filed on 7/29/2010, NPL #66), as applied to claim 46 above, and in further view of Boneau US 5,879,382.

The combination of Dovesi and Lendlein disclose the invention as discussed above but does not disclose, flooding the retention device with a liquid bath.

Boneau discloses a device made out of a shape memory material that is activated/ expanded by the use of heated fluids to cause expansion (see Col 2 lines 46-55).

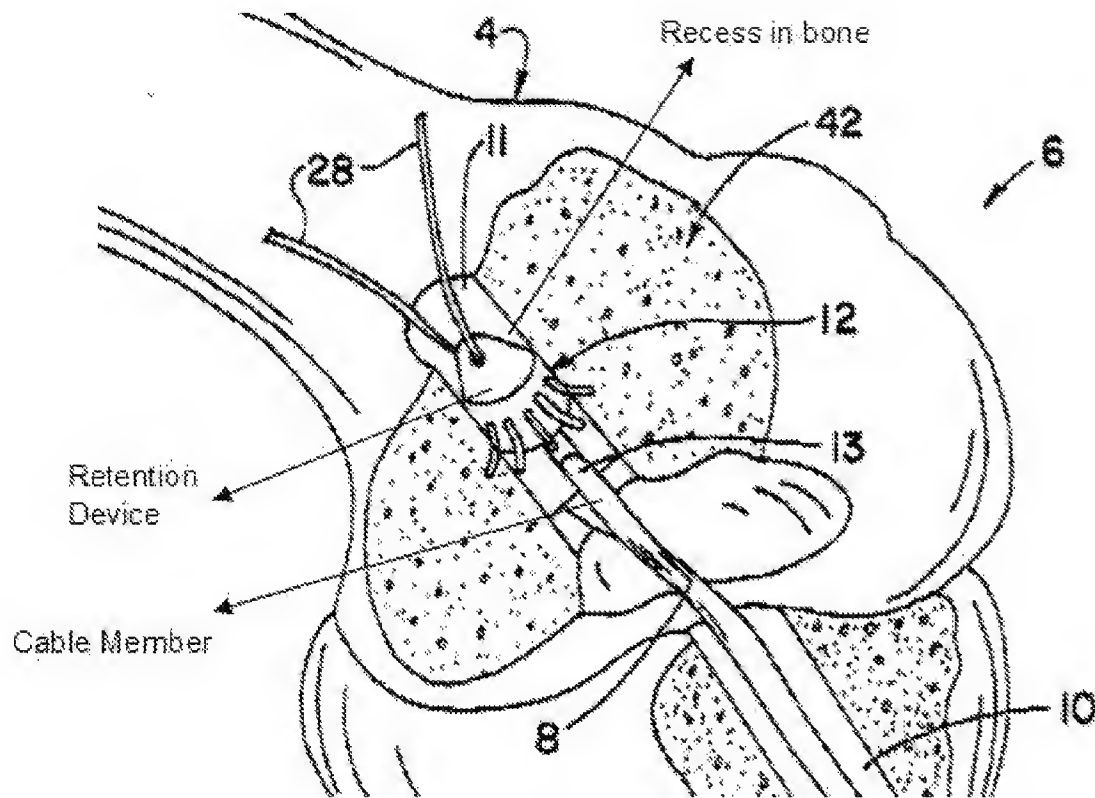
It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of combination of Dovesi and Lendlein to use a liquid bath in view of Boneau because it applies a known technique to a known device ready for improvement to yield predictable results of helping expand a shape memory material, where heated fluids provide a known way for heating a shape memory material to change it's shape. .

Claims 46, 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li US 5,505,735 in view of Lendlein et al (see IDS filed on 7/29/2010, NPL #66) .

Regarding **Claim 46**, Li discloses a method comprising:

inserting a cable member (#8) into a recess in a bone (see Fig below);

inserting a retention device (#12) into the recess, the retention device containing a shape memory material; and activating the shape memory material that causes that shape memory material to change shape (see Col 7 lines 20-30, where the retention device is made out of a shape memory material and changes shape).



Regarding **Claim 56**, Li discloses inserting the cable member operation is performed simultaneously with the inserting of the retention device operation (see Fig above in claim 46, Fig 2, Col 8 lines 30-53, wherein the retention device has a hole for sutures #28 and a hole #30 for the cable member, where the sutures is pulled, wherein inserting the cable member and retention member is simultaneously performed).

Li discloses the use of a shape memory material, where the barb #36 extends outward to a larger shape to fixate the retention member and cable member in bone but does not disclose the retention device containing a shape memory polymer such that is inserted in a temporary pre-implantation shape and causing the polymer to change shape after implantation.

Art Unit: 3733

However, Lendlein discloses that shape memory polymers allow for implants to be placed through small incisions (see introduction on page 1673), wherein shape memory polymers possess the ability to memorize permanent shape that can substantially differ from their initial temporary shape, wherein bulkier devices can be introduced into the body in a compressed temporary shape then expanded on demand to a permanent shape to fit as required (see last paragraph at the end of page 1673 continuing to the top paragraph of page 1674), wherein the shape memory polymer can be activated by heating (see page 1674, 2nd and 3rd paragraphs starting with “The thermally induced shape memory effect ...”).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Li to include a shape memory polymer in view of Lendlein because shape memory polymers are known shape memory materials, wherein a shape memory polymer is a simple substitution of one known shape memory material for another to obtain predictable results of expanding a shape memory material from a pre-implantation state to a post-implantation state, wherein shape memory polymers allow for implants to be placed through small incisions, where shape memory polymers possess the ability to memorize permanent shape that can substantially differ from their initial temporary shape, wherein bulkier devices can be introduced into the body in a compressed temporary shape. The combination of Li and Lendlein would still allow for the retention device to be inserted in a smaller pre-implantation shape, where after the shape memory polymer is activated, the retention device would change to a larger shape, thereby providing fixation for the retention member in the bone as well as

Art Unit: 3733

the cable member, wherein the use of the shape memory polymer would allow one to better control of the pre-implantation shape and the post-implantation shape to fixate the retention device and cable member.

(10) Response to Argument

The appellant argues that Dovesi does not disclose the shape memory material as material changing shape and activating the shape memory material. The examiner disagrees as Dovesi clearly states in paragraph 30 that the device can be made out of shape memory material. One of ordinary skill in the art knows that shape memory materials are known for their ability to change shape when activated, hence the name used to describe them, which is in contrast to non-shape memory materials that have a fixed shape. While Dovesi does not go into much detail about the use of shape memory materials, it is known within the art that there is a shape change feature of shape memory materials.

Likewise, the rejection was made in view of the combination of Dovesi and Lendlein and that there is no reason to combine the references and that the combination would fail to operate. In response to appellant's argument that there is no teaching, suggestion, or motivation to combine the references, the examiner recognizes that obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5

Art Unit: 3733

USPQ2d 1596 (Fed. Cir. 1988), *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), and *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007). In this case, Lendlein disclose that shape memory polymers possess the ability to memorize permanent shape that can substantially differ from their initial temporary shape, wherein bulkier devices can be introduced into the body in a compressed temporary shape (see last paragraph at the end of page 1673 continuing to the top paragraph of page 1674), wherein the shape memory polymer can be activated by heating (see page 1674, 2nd and 3rd paragraphs starting with "The thermally induced shape memory effect ..."). As such, Dovesi already discloses the use of shape memory materials. Lendlein discloses a known type of memory material, shape memory polymers. One of ordinary skill in the art can recognize that the device of can have a smaller implantation shape and once activated, can expand to it's original shape. Furthermore, the combination of Dovesi and Lendlein would allow for a smaller incision and a smaller hole in the bone, where the device of Dovesi can be implanted as described, where when in place, it can be activated by, for example, heat, the device can be expanded back to a larger original shape. This allows the device is able to press further against the bone and enhance fixation of the cable member against the bone. The examiner notes that one of ordinary skill in the art would take into consideration the size difference between the implantation shape and post implantation shape.

The appellant also argues that the shape memory polymer of Lendlein is for low force and is out of the range to fixate a tendon to bone. In response to appellant 's arguments against the references individually, one cannot show nonobviousness by

Art Unit: 3733

attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Leindlein gives an example of the use of the shape memory polymer and one of ordinary skill in the art will recognize having the teachings of Leindlein before him or her with common knowledge in the art to provide a shape memory polymer with sufficient strength to be placed in the bone. A person of ordinary skill in the art is also a person of ordinary creativity, not an automaton.”KSR, 550 U.S. at ___, 82 USPQ2d at 1397. “[I]n many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle.”Id. Office personnel may also take into account “the inferences and creative steps that a person of ordinary skill in the art would employ.”Id. at ___, 82 USPQ2d at 1396.

With regards to Li, the appellant points out that the barbs are made out of a shape memory alloy and do not have a memorized shape. However, the examiner notes that the rejection was made in combination of Li and Lendlein and as pointed out in the last office action, Li does not disclose a shape memory polymer that is inserted in a temporary pre-implantation shape and causing the polymer to change shape after implantation.

Appellant argues that there is no reason to combine the references and that the combination would fail to operate. In response to appellant’s argument that there is no teaching, suggestion, or motivation to combine the references, the examiner recognizes that obviousness may be established by combining or modifying the teachings of the

Art Unit: 3733

prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), and *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007). In this case, Lendlein disclose that shape memory polymers possess the ability to memorize permanent shape that can substantially differ from their initial temporary shape, wherein bulkier devices can be introduced into the body in a compressed temporary shape then changed to a larger shape to fix the device (see last paragraph at the end of page 1673 continuing to the top paragraph of page 1674), wherein the shape memory polymer can be activated by heating (see page 1674, 2nd and 3rd paragraphs starting with "The thermally induced shape memory effect ..."). With the combination of Li and Lendlein, the barbs of Li are still able to be implanted in a smaller state and once in place in the soft cancellous area of the bone, the barbs can be activated to expand to enhance the fixation of the barbs in the bone tunnel. In the original shape, the barbs are able to dig further into the surrounding bone to fix the tendon in place. The shape memory polymer with the ability providing one with better control of the pre-implantation shape and the post-implantation shape due to the memory effect of shape memory polymers.

The appellant also argues that the shape memory polymer of Lendlein is for low force and would not have enough strength if applied to Li. In response to appellant's arguments against the references individually, one cannot show nonobviousness by

Art Unit: 3733

attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Leindlein gives an example of the use of the shape memory polymer and one of ordinary skill in the art will recognize having the teachings of Leindlein before him or her with common knowledge in the art to provide a shape memory polymer with sufficient strength to be placed in the bone. A person of ordinary skill in the art is also a person of ordinary creativity, not an automaton.”KSR, 550 U.S. at ___, 82 USPQ2d at 1397. “[I]n many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle.”Id. Office personnel may also take into account “the inferences and creative steps that a person of ordinary skill in the art would employ.”Id. at ___, 82 USPQ2d at 1396. The appellant is not claiming a specific range or value for the strength of the shape memory polymer. Likewise, as stated in the previous office action, appellant has provided numerous references which highlight the benefits of using shape memory polymers.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner’s answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Art Unit: 3733

/Jan Christopher Merene/

Examiner, Art Unit 3733

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/EDUARDO C. ROBERT/

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